

## APPROVED PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS:

S3

#### **PARACETAMOL FRESENIUS 10 mg/ml (50 ml)**

#### **PARACETAMOL FRESENIUS 10 mg/ml (100 ml)**

Solution for intravenous infusion

**PARACETAMOL FRESENIUS 10 mg/ml (100 ml):** Each 100 ml bottle contains 1 g of paracetamol.

**PARACETAMOL FRESENIUS 10 mg/ml (50 ml):** Each 50 ml bottle contains 0,5 g of paracetamol.

Contains sugar

**Read all of this leaflet carefully before you are given PARACETAMOL FRESENIUS 10 mg/ml solution.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- PARACETAMOL FRESENIUS 10 mg/ml has been prescribed for you personally, and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

#### **What is in this leaflet**

1. What PARACETAMOL FRESENIUS 10 mg/ml is and what it is used for
2. What you need to know before you are given PARACETAMOL FRESENIUS 10 mg/ml
3. How PARACTEAMOL FRESENIUS 10 mg/ml is administered
4. Possible side effects
5. How to store PARACETAMOL FRESENIUS 10 mg/ml
6. Contents of the pack and other information

#### **1. What PARACETAMOL FRESENIUS 10 mg/ml is and what it is used for**

PARACETAMOL FRESENIUS 10 mg/ml is used in adults and children of at least 1 year old (and

weighing at least 10 kg) for:

- the short-term treatment of mild to moderate pain such as dental procedures, minor surgery, and for
- the short-term treatment of fever when medicine cannot be swallowed.

## **2. What you need to know before you are given PARACETAMOL FRESENIUS 10 mg/ml**

**PARACETAMOL FRESENIUS 10 mg/ml should not be administered to you:**

- If you are hypersensitive to paracetamol, pro-paracetamol hydrochloride, or any of the ingredients in Paracetamol Fresenius 10 mg/ml (see WHAT PARACETAMOL FRESENIUS 10 mg/ml CONTAINS).
- If you have severe liver disease including alcoholic liver disease.
- Patients weighing less than 33 kg.

### **Warnings and precautions**

Tell your doctor or health care provider before being given the injection:

Take special care with PARACETAMOL FRESENIUS 10 mg/ml

Tell your doctor or healthcare professional before being given the injection:

- if you are able to take medicine orally instead of an infusion;
- if you are using any other medications containing paracetamol;
- if you have any history of liver damage;
- if you have any history of kidney damage;
- if you are using alcohol;
- if you suspect that you may be undernourished or dehydrated;
- if you are pregnant or breastfeeding your baby (see **Pregnancy and breastfeeding**).

### **Other medicines and PARACETAMOL FRESENIUS 10 mg/ml**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

The use of probenecid (medicine for treatment of gout) and salicylamide (medicine for treatment of pain and fever) may interfere with the clearing of paracetamol by the liver. Phenytoin (medicine used

for epilepsy) may cause damage to the liver. Caution should be taken when using enzyme-inducing substances with Paracetamol Fresenius 10 mg/ml such as barbiturates, rifampicin, isoniazid, anticoagulants, zidovudine and chronic use of alcohol.

**Flucloxacillin:** Caution is advised when paracetamol is administered concomitantly with flucloxacillin due to the increased risk of high anion gap metabolic acidosis (HAGMA), particularly in patients with a risk factor for glutathione deficiency such as severe renal impairment, sepsis, malnutrition and chronic alcoholism. Close monitoring is recommended in order to detect the appearance of acid base disorders, namely HAGMA, including the search of urinary 5-oxoproline.

### **Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine. Special care should be taken if you are pregnant, planning to become pregnant or breastfeeding your baby, as safety in pregnancy and breastfeeding has not been established.

### **Driving and using machines**

It is not always possible to predict to what extent PARACETAMOL FRESENIUS 10 mg/ml may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which PARACETAMOL FRESENIUS 10 mg/ml affects them.

Paracetamol Fresenius 10 mg/ml usually has no influence on the ability to drive or use machines. Do not drive, or use machinery or tools until you know how Paracetamol Fresenius 10 mg/ml affects you.

### **3. How PARACTEAMOL FRESENIUS 10 mg/ml is administered**

Do not share medicines prescribed for you with any other person. **For single use only.**

#### **Adults:**

The dose of Paracetamol Fresenius 10 mg/ml will be different for different patients.

Paracetamol Fresenius 10 mg/ml is for intravenous use only. Your doctor will decide on a suitable dose and the duration of the treatment based on your specific condition and needs.

**Children:**

Your child's doctor will work out what dose your child should receive, based on his/her weight.

Paracetamol Fresenius 10 mg/ml is usually only given to children if they are older than 1 year or weigh more than 10 kg. Tell your child's doctor if you have given any other paracetamol containing pain medication to your child. The doctor needs this information to work out how much Paracetamol Fresenius 10 mg/ml your child can receive.

**If you receive more PARACETAMOL FRESENIUS 10 mg/ml than you should**

Paracetamol Fresenius 10 mg/ml is for intravenous use only. **Since a health care provider will administer PARACTEAMOL FRESENIUS 10 mg/ml, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.** If you receive higher doses than recommended, it can cause severe liver damage. The symptoms of liver damage are usually seen first after 2 days with the most severe symptoms experienced after 4 – 6 days. You may experience nausea, vomiting, anorexia (refusing to eat), pallor (pale skin) and abdominal pain and your doctor will treat these symptoms symptomatically. You may also have liver damage which will be indicated by high blood levels of liver enzymes.

**If you missed a dose of PARACETAMOL FRESENIUS 10 mg/ml**

Paracetamol Fresenius 10 mg/ml is for intravenous use only and your doctor will make sure that you receive Paracetamol Fresenius 10 mg/ml at the right time, therefore it is unlikely that the dose will be missed.

**4. Possible side effects**

PARACETAMOL FRESENIUS 10 mg/ml can have side effects.

Not all side effects reported for PARACETAMOL FRESENIUS 10 mg/ml are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking

PARACTEAMOL FRESENIUS 10 mg/ml, please consult your health care provider for advice.

The following side effects may occur less frequently:

- Hypersensitivity and allergic reactions: any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips and rash or itching (especially affecting your whole body), flushing (redness of the skin) should be reported to a doctor immediately.
- Angioedema (swelling of the affected area with a burning sensation).
- Blood disorders characterised by unusual tiredness or weakness.
- A quick heart-beat
- Low blood pressure, flushing of the skin
- Liver problems (you may notice signs like dark urine, pale-coloured stools, yellow skin and eyes, abdominal pain)
- Skin rash, itching, redness of skin and other skin conditions
- Kidney problems (you may notice signs like cloudy urine, need to urinate frequently, burning urine and back pain)
- General feeling of unease, weakness or discomfort
- Nausea and vomiting, stomach pain
- Pain and burning at the site of the injection.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### **Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of PARACETAMOL FRESENIUS 10 mg/ml.

### **5. How to store PARACETAMOL FRESENIUS 10 mg/ml**

Store all medicines out of reach of children.

Store at or below 30 °C.

Do not refrigerate or freeze.

Once opened, the contents should be used immediately.

Discard any unused portion.

## **6. Contents of the pack and other information**

### **What PARACETAMOL FRESENIUS 10 mg/ml contains**

#### **Paracetamol Fresenius 10 mg/ml (100 ml):**

Each 100 ml bottle contains 1 g of paracetamol.

#### **Paracetamol Fresenius 10 mg/ml (50 ml):**

Each 50 ml bottle contains 0,5 g of paracetamol.

**Inactive ingredients:** Mannitol, water for injection, nitrogen

Contains 0,01 % m/v cysteine (as antioxidant)

Osmolality: 280 mOsm/l

### **What PARACETAMOL FRESENIUS 10 mg/ml looks like and contents of the pack**

Packed into 50 ml or 100 ml clear, colourless glass bottles with a red rubber stopper and an aluminium cap, with either a tear-off tab of aluminium or a plastic lid.

10, 12 or 20 bottles of 50 ml or 100 ml each are packed with a package insert into a cardboard box.

Clear, colourless to slightly yellowish solution free from visible particulate contamination.

### **Holder of Certificate of Registration**

Fresenius Kabi South Africa (Pty) Ltd

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2 Tonetti Street,

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1682

### **This leaflet was last revised in**

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